Validation and Optimization of the Trigger Tool for the Detection of Adverse Events in General Surgery.

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Research Article

Keywords: adverse event, General surgery, Trigger tool

Posted Date: October 25th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-994215/v1>

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Abstract

Background

General surgery is an area with a major incidence of adverse events and entails increased use of resources, in addition to the injury caused to the patient. The preparation of specific tools in the field of patient safety and specifically to detect adverse events is a priority of healthcare systems. Regarding the hypothesis that the trigger tool is effective to detect adverse events in general surgery we set out this study with the aim to validate this and propose optimization.

Methods

Observational, descriptive, retrospective and multicenter national study where trigger tool (40 triggers) was applied in patients who underwent surgery in general surgery departments.

A descriptive analysis was performed. The tool's sensitivity and specificity was studied by means of looking at predictive capacity. A prediction model was used for the proposed optimization by means of binary logistic regression

Results

A total of 31 hospitals took part. The prevalence of adverse events was 31.53%.

The tool revealed sensitivity and specificity of 86.27% and 79.55%, respectively. A total of 12 triggers comprised the optimized model. An area under the curve of 79.29% was obtained.

Conclusions

Trigger Tool is extremely effective to detect adverse events during surgery. The optimized model significantly reduces the number of triggers used and upholds

Background

Identification of adverse events (AE) is relevant for patient safety. The overall rate of AE during hospitalization varies from 3–17%, of which approximately 50% are deemed preventable¹.

AE entail a clinical impact and an increase in resources. The most expensive are surgical, those related to medication and diagnostic delay².

Surgical units are the areas with the highest frequency of AE. They are related to 1.9–3.6% of AE in patients admitted to hospital, which represents 46–65% of all AE in hospitalization^{3,4}.

The most usual AE methods to detect AE (reporting of incidents, record of incidents and clinical-administrative databases) tend to underestimate the actual number of AE. Since the publication of the Harvard Medical Practice Study (HMPS), the retrospective methodology to review AE has been the most commonly used.

In 2006 the Institute for Healthcare Improvement (IHI) encouraged healthcare systems to implant the Global Trigger Tool to measure and monitor injury to the patient.

In general surgery the trigger tool presented sensitivity and specificity of 86.0% and 93.6% respectively. This means it is highly effective to detect AE².

Development of a specific tool that enables identifying AE at low cost, quickly and effectively is of major use in surgery.

The aim of this study is to validate a set of predictive “triggers” for AE in patients operated in General Surgery and Gastrointestinal System (GSGS) departments.

Material And Methods

Study design

Observational, descriptive study with analytical, retrospective and multicenter components to validate the trigger tool for detection of AE in GSGS.

A total of 31 acute care hospitals from the public health system took part in the study (sampling by convenience).

Patients aged over 18 admitted to GSGS from 01-09-2017 to 31-05-2018 who underwent surgery, with full and closed clinical histories and hospital discharge from the same hospital, were included.

Psychiatric, transplanted patients and those referred from other hospitals were excluded.

The sample was calculated randomly according to an estimated probability of 90% for detection of AE², with an estimated population of 80,000 patients, a 95% confidence interval and precision of 0.02. Sample size was 855 histories distributed among the hospitals taking part. The sample was enlarged to avoid possible case losses and incomplete information.

Instrumentalization

The trigger tool (TT) was applied to detect AE. A total of 40 triggers were included (Table 1).

For the category of AE injury the “National Coordinating Council for Medication Error Reporting and Prevention” classification (Figure 1) was used.

A screening guide was published in accordance with criteria on the search for triggers and AE and a training video-tutorial. When necessary the training was completed with an individual tutorial.

Review process

Each center had at least two reviewers.

Clinical histories were reviewed in accordance with the screening guide to identify triggers. Both histories that contained triggers and those that did not were reviewed to search for AE. The same information sources and review sequences were used.

Information sources were clinical discharge reports, surgical procedure protocols, medical and nursing clinical course observations from the patient's admission to 30 days post-discharge, reports of additional tests and prescription of medicines.

AE was considered to be any harmful and unintended event that occurred to the patient as a consequence of the practice of healthcare unrelated to their illness.

When an AE was detected an injury category was assigned and the degree to which this could have been prevented was assessed. The classification used in the ENEAS study was adapted to determine the preventable nature of the AE.

The study data and variables were recorded in an online database (REDCap). Confidentiality rules were upheld.

This study was approved by the coordinator site's ethics committee.

Statistical method

Descriptive analysis by means of mean, median and standard deviation for continuous variables and by means of distribution of frequencies for categoric variables.

The most important variables were compared by means of Mann-Whitney U non-parametric contrast, chi-squared contrast or Fisher test.

To measure the predictive validity of the tool to detect AE, diagnostic sensitivity and specificity, in addition to positive predictive value (PPV) and negative predictive value (NPV) were used.

A prediction model was used for the proposed optimization of the tool by means of binary logistic regression. The onset of AE and triggers were introduced as dependent and independent variables, respectively. The latter were the statistically significant ones on bivariate analysis.

The model's results are shown in the form of odds ratio (95% confidence interval [CI]). The model's discriminatory power was assessed by means of area under the curve (ROC).

The prediction model was repeated for relevant clinical entities such as preventable and severe AE and most common procedures.

$P < 0.05$ was considered statistically significant for all analyses.

Data were entered by each center's reviewers into the REDCap database. The statistics program STATA/SE v10.0 was used.

This study has been funded by Instituto de Salud Carlos III through the project "PI17/01374" (Co-funded by European Regional Development Fund/European Social Fund; "A way to make Europe"/"Investing in your future").

The project was approved by the ethics committee of the study coordinating center.

Results

A total of 31 hospitals took part, 10 type 1 (under 300 beds), 7 type 2 (301-600 beds) and 14 type 3 (more than 601 beds). A total of 1132 cases were recorded. Mean age was 58.15 (18-94). There were 555 (49%) females and 577 (51%) males.

Symptomatic cholelithiasis was the most common diagnosis. This accounted for 13.1% of the total, followed by acute appendicitis (7.2%) followed by inguinal hernia (7.9%), breast neoplasia (5.5%) and eventration (4.9%).

The most common procedures were cholecystectomy (17%), both inguinal and umbilical hernioplasty (13%), appendectomy (7%), eventroplasty (5%) and mastectomy (3%).

Mean stay was 6.5 days (standard deviation 14.32). A total of 73.7% and 26.1% were scheduled and emergency surgical procedures, respectively.

Behavior of the tool

The tool revealed sensitivity and specificity of 86.27% and 79.55%, respectively. PPV and NPV were 66.52% and 92.48%, respectively. For severe AE, sensitivity and specificity were 100% and 26.5%, respectively. For preventable AE sensitivity and specificity were 90.3% and 66.9%, respectively.

Table 2 shows the 38 triggers which, after bivariate study, were statistically significant with the onset of AE and their onset frequency.

The triggers that comprised part of the optimized models are shown in Table 3. The model for total AE had 12 triggers. Its predictive capacity is shown in Table 4, its ROC was 83.36 % (CI 81.14%-85.83%).

For preventable AE the optimized model led to obtaining sensitivity and specificity of 83.6% and 74.95%, respectively. ROC was 79.29% (CI 76.14%-82.4%).

Adverse events

The prevalence of AE was 31.53% (357 patients). There was a total of 599 AE. A total of 69 patients presented a second AE (6.10%) and 28 a third AE (2.47%). A total of 16 patients had four or more AE (1.41%).

The most commonly observed AE were infections (35%). The most common was infection of the surgical site followed by paralytic ileus, intra-abdominal abscess and anastomotic fistula.

The category of AE injury is shown in Graph 1. A total of 34% of AE were deemed preventable.

Discussion

The most important contribution of this study is validation of the TT in GSGS and the proposal for the first time of an optimized model. This enables detecting AE more efficiently, which is extremely useful to improve patient safety.

Methodology for validation of the trigger tool.

TT validation studies have been performed in other specialties. Some works have also published results on optimization of the tool in different areas. This study is to date the first on validation of the TT in GSGS and also the first proposed optimized model for this specialty.

One of the methods used to validate the tool was the opinion of experts with Delphi-like surveys on the triggers included in an initial proposal. For some of them the final model included those with a PPV greater than 5%¹⁹. In others a subsequent study was performed for its validation by means of calculating false negatives in a random sample²⁰.

Some works report the review of trigger histories. This is the case of the Israeli study on TT in AE related to medication. The optimized model proposed was prepared in accordance with PPV over 10% and the opinion of a panel of experts removing four of the 17 initial triggers. This study only reports AE related to medication and the final model is not based on multivariate statistical analysis.

Predictive capacity of the optimized tool

In regard to the predictive capacity of optimized models we found that the study whose results are most similar to this work is the one that uses a similar methodology. In the study by Griffey its model's area under the curve was 82% with 12 triggers compared to 83.6% in our study.

The PPV of our model (66%) is much higher than that reported in the remaining publications where other methodologies were used with PPV 28.5%¹⁹ and 22.1%²² where the selection of triggers is not sufficiently accurate.

The studies detected to date do not report specificity or NPV of the tools used as the histories ruled out that did not contain triggers were not reviewed.

Adverse events

The prevalence of AE detected in our study is greater than that reported in studies on AE¹⁷ but similar to that reported in studies where the trigger methodology was used in 7–40% of hospitalized patients²⁰.

In a scope review performed by Schwendimann et al. it was concluded that half the AE were deemed preventable compared to 34% in our study⁷. The variability and subjectivity in regard to the preventability of AE was discussed previously. It was recommended not to use this kind of measure.

In regard to the severity of AE, the most common injury category was F with 58%, followed by category E. These outcomes coincide with those reported in the literature²⁴.

Limitations

The national study required a large number of reviewers and there may be a certain degree of variability.

The use of HT to identify AE may not capture all AE and information sources may not be reliable. These limitations are part of the IHI's own methodology.

Strengths

Validation was performed in a multicenter study including different kinds of hospitals inside the national health system.

However, there was a special focus on training reviewers and homogenization of criteria with close tutoring by the research team.

Research collaboration

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Conclusions

The TT proposed in this study is effective to detect adverse events in general surgery and shows high sensitivity and specificity.

The tool's optimized model has good predictive capacity.

Abbreviations

Adverse event (AE)

Institute for Healthcare Improvement (IHI)

General Surgery and Gastrointestinal System (GSGS)

The trigger tool (TT)

Positive predictive value (PPV)

Negative predictive value (NPV)

Area under the curve (ROC).

Confidence interval (CI)

Declarations

FOUNDING

This study was subsidized by the European Regional Development Fund ("A way to make Europe") by means of a research grant awarded by the Spanish Ministry of Economy, Industry and Competitiveness of the Government of Spain, through Carlos III Health Institute.

STATEMENTS TO COMPLY WITH ETHICS REQUIREMENTS

The research project was approved by the 12 de Octubre University Hospital Ethics Committee.

CONFLICTS OF INTEREST

None of the authors have any conflict of interest to declare in regard to the performing or publication of this work.

INFORMED CONSENT

According to the ethics committee's assessment and given the research project's observational, descriptive and non-interventionist methodology, informed consent was not required from the patients included in the study.

We acted in accordance with the prevailing data protection law and rules that regulate the processing of patient information by the Spanish health system.

CONTRIBUTIONS OF AUTHOR

AIPZ was the principal investigator of the study. Together with ERC and PRL they developed the research project that was eligible for the Carlos III Institute grant.

MFB was in charge of coordinating the team of collaborators in the centers participating in the study. CLS and EFH facilitated contact with reference centers and provided methodological support for the resolution of doubts to the participants. Lastly, CMA, MTG and AIPZ performed the statistical analysis.

CONSENT TO PARTICIPATE

Not applicable

This manuscript does not report on or involve the use of any animal or human data or tissue.

Not applicable

Acknowledgements

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Tables

Table 1
Triggers used in the study grouped by modules

MODULES	TRIGGERS USED IN THE STUDY
Care module	<ol style="list-style-type: none"> 1. Transfusion of blood or blood derivatives 2. Cardiorespiratory arrest code 3. Acute dialysis 4. Positive blood culture 5. Radiological test for the study of thrombosis (Unscheduled echo-Doppler during admission, CT angiography) 6. Sudden decrease in hemoglobin equal or greater than 25%. 7. Patient fall 8. Bedsores 9. Patient detention measures 10. Readmission 30 days post-discharge 11. Unscheduled radiology during admission 12. Infection associated with healthcare
Medication module	<ol style="list-style-type: none"> 1. Positive culture for Clostridium difficile antihistamine 2. Partial Thromboplastin Time (PTT) over 100 s 3. INR (International Normalized Ratio) over 6 4. Glycemia under 50 mg/dL 5. Increased serum creatinine x 2 compared to basal level 6. Administration of vitamin K 7. Administration of Flumazenil 8. Administration of Naloxone. 9. Administration of Epinephrine. 10. Administration of anti-emetics 11. Sudden stoppage of the medication
Surgical module	<ol style="list-style-type: none"> 1. Reintervention in the 30 days post-discharge. 2. Unscheduled change in procedure or complication of this. 3. Unscheduled transfer to critical care unit (higher level of care) 4. Unscheduled intubation or repeat intubation 5. Intra-operative radiology 6. Mechanical ventilation greater than 24 hours 7. Intra-operative administration of Flumazenil, Naloxone or Epinephrine. 8. Postoperative increase in troponin greater than 1.5 nanograms/mL 9. Unscheduled injury or removal of an organ

MODULES	TRIGGERS USED IN THE STUDY
Added based on prior literature and studies	<ol style="list-style-type: none"> 1. Care in the emergency department 30 days post-discharge 2. Unscheduled invasive procedures during admission (interventional radiology, endoscopy) 3. Pathological anatomy unrelated to diagnosis 4. Use of broad spectrum antibiotherapy 5. Use of Total Parenteral Nutrition. 6. Prolonged stay in resuscitation after surgery (over 24 hours).

Table 2
Trigger and onset of Adverse Event

Trigger	Frequency	<i>P</i>
Broad spectrum antibiotherapy	171	0.014
Unscheduled radiology	162	0.013
Emergencies 30 days	112	0.012
Re-intervention	80	0.011
Post-operative TPN	73	0.011
Use of Vitamin K	71	0.001
Transfusion of blood derivatives	65	0.013
Stay in resuscitation >24 h	63	0.013
Decrease in Hb >2 g/24 hours	59	0.01
Unscheduled ITU transfer	55	<0.001
Readmission after 30 days discharge	54	0.009
Invasive procedures	53	0.009
Transfer to critical care unit	51	0.009
Scheduled change in procedure	38	0.00863
Basal creatinine x 2	36	0.008
Mechanical ventilation over 24 hours	30	0.00742
Use of Naloxone	30	0.00758
Positive Blood culture	30	0.00746
Unscheduled injury of removal of an organ	24	0.00728
Reintubation	21	0.006
Pathologic anatomy unrelated to diagnosis	20	0.006
Unscheduled intubation	18	0.005
Sudden stoppage in medication	13	0.0052
Cardiorespiratory arrest	12	0.00479
Pressure sore	10	0.004
Detention measures	9	0.004
Intra-operative radiology	8	0.004
Acute dialysis	5	0.003
Antihistamine	3	0.002
Post-operative troponin over 1.5 ng/mL	3	0.002
Patient fall	2	0.001
Positive stool culture	1	0.001
Flumazenil	1	0.001
Naloxone	1	0.001

Table 3
Predictive capacity of the optimized model for the
total AE (12 triggers)

	Value	95% confidence interval	
Sensitivity	83.47	79.48	87.47
Specificity	83.25	80.52	85.97
Validity index	83.32	81.09	85.55
PPV	70.12	65.65	74.59
NPV	91.45	89.29	93.61

Table 4. Optimized models and triggers included

OPTIMIZED MODELS						
TRIGGERS	TOTAL AE	PREVENTABALE AE	SEVERE AE	CHOLECYSTECTOMY	COLORECTAL CANCER	APPENDECTOMY
Broad spectrum antibiotherapy	✓	✓	✓	✓	✓	✓
Unscheduled postoperative radiology	✓	✓	✓	✓	✓	✓
Re-intervention	✓	✓		✓	✓	
Emergencies 30 days after discharge	✓	✓				✓
Transfer to critical unit	✓	✓			✓	
Readmission 30 days after discharge	✓				✓	
Stay for 24 hours in resuscitation	✓	✓			✓	
Invasive procedures	✓					
Scheduled change in procedure	✓					
Organ damage-removal	✓					
Sudden fall in hemoglobin	✓				✓	
Use of postoperative parenteral nutrition	✓					
Blood transfusion		✓		✓	✓	
Use of vitamin K				✓		
Basal creatinine x 2.				✓		✓
Mechanical ventilation 24 hours			✓			
Injury-removal of an organ					✓	✓
Re-intubation			✓		✓	
AREA UNDER THE CURVE	83.36% (CI 81.14%-85.83%).	79.29% (CI 76.14%-82.4%)	67.72% (CI 57.2%-68.91%)	64.33% (CI 58.43%-68.9%)	67.67% (CI 62.31%-73.02%)	58.50% (CI 52.97%-64.04%)

✓ existence of trigger

Figures

Figure 1

AE by injury category Category E: temporary injury to the patient that requires intervention; category F: temporary injury to the patient that requires readmission or prolonged hospital stay; category G: permanent injury to the patient; category H: injury that requires essential intervention to keep the patient alive; category I: injury that leads to the patient’s death.